No new matter has been added by these amendments. Reconsideration and withdrawal of the rejections in light of the preceding amendments and following remarks are respectfully requested.

English Translation

As requested by the Examiner, Applicants hereby submit with this amendment an English translation of Voigt, R: "Therapeutische Systeme," Pharmazeutische Technologie, pages 556-557 (1993).

Extension of Time

A petition for a three-month extension of time and the fee therefore accompanies this response.

The Rejection Under 35 U.S.C. §103(a)

Claims 1-34 were rejected under 35 U.S.C. §103(a), as obvious over Dong et al. (U.S. Patent No. 5,770,227) and Patrick et al., Biopharmaceuticals & Drug Disposition, 10:165-171 (1989). With regards to claims 1-34, this rejection is respectfully traversed. To the extent the rejection may apply to new claims (35-47), it is also traversed.

Dong et al. relate to a therapeutic composition of progesterone for hormone replacement therapy (column 1, lines 10-16). A bilayer core dosage form is employed for dispensing the progesterone to the gastrointestinal tract of a human. The dosage form contains a progesterone layer and a push layer (Example 7). The bilayer core may also contain an interior surface facing the bilayer core and an exterior surface coated on its exterior surface with a semipermeable wall. (Example 11). The bilayer dosage form may also contain an osmagent (Example 15). Finally, the invention also provides a method for administering progesterone for hormone replacement therapy 10 ng to 1200 mg over a period of 30 hours (column 7, lines 19-21).

Patrick et al. provide a perspective on the absorption of sustained-release methylphenidate formulations compared to immediate release formulations (page 165). This perspective is provided by comparing 3 products: a 10 mg tablet of MPH-IR Ritalin®, a 20 mg tablet of MPH-SR Ritalin®, and a newly formulated 20 mg tablet of MPH-SR from MD Pharmaceuticals (Santa Ana, Ca) (page 166). The authors concluded that the three formulations demonstrated were equivalent in the extent of absorption (page 170).

Applicants respectfully traverse this rejection for a number of reasons. Establishment of a *prima facie* case of obviousness requires that the cited documents teach or suggest all of the limitations of the rejected claims. In addition, some suggestion or motivation must be provided to modify the documents to reach the claimed invention. Further, a document must be considered as a whole, including those portions of the document that teach away from the claimed invention.

Applicants respectfully submit that all of elements recited in claims 1-47 are not taught or suggested by Dong et al. and Patrick et al. Moreover, Applicants further submit that one of skill in the art would not be motivated to prepare a dosage form as recited in Applicants' claims.

Dong et al. fail to teach or suggest any dosage form containing a longitudinally compressed tablet core. As stated in Applicants specification at page 19, lines 8-13, Applicants' unique LCT configuration ensures that, as the push layer expands longitudinally with the compartment formed by the semipermeable membrane, the surface area of the push layer in contact with the semipermeable membrane is increased more than when other configurations are used, i.e., the configuration taught by Dong et al.

Additionally, Dong et al. do not teach or suggest a dosage form that releases drug at an ascending release rate as claimed by Applicants. Dong et al. merely provide an "acceptable oral means for administering progesterone at a controlled does over time," (column 1, lines 46-48). Moreover, Dong et al. fail to teach or suggest any dosage form containing a trilayer formulation. Dong et al. relate only to a bilayer tablet. And, as pointed out by the Examiner, Dong et al. fail to teach or suggest a CNS acting drug, such as methylphenidate.

The secondary reference, Patrick et al., fails to supply that which is missing from Dong et al. Specifically, Patrick et al. merely provide a perspective on the absorption of sustained-release methylphenidate formulations compared to immediate release formulations. No teaching, suggestion or motivation is provided for the dosage forms and methods as claimed by Applicants.

For the above reasons, Applicants respectfully submit that the invention recited in claims 1-47 are patentable over Dong et al. in view of Patrick et al. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) are respectfully requested.

Conclusion

In light of the remarks presented herein, it is respectfully submitted that pending claims 1-47 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representative at the below-listed telephone number if it is believed that prosecution of this application may be assisted thereby.

CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on this 30 day of NOV, 2000.

Paul B. Simboli

30 NOV 2000
Date

Respectfully Submitted,

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